REMARKS

In response to the Office Action mailed on January 29, 2004, the Applicant respectfully requests reconsideration. Claims 1-9 and 35 of restricted group II are obvious over pending claims 10, 12-13, 15-18, 20-23, 25-29, and 32-34 of restricted group I and are presented for examination. Claims 1, 10, 20, 21, 28, and 38 are independent claims and the remaining claims are dependent claims. In this Amendment, claims 1, 2, 5-9, 10, 12, 20, 21, 28, and 32-34 have been amended and claims 3, 4, 24 and 36 have been cancelled. Claims 37-40 have been added by the present amendment and do not add new matter to the application. Claims 1-2, 5-10, 12-13, 15-18, 20-23, 25-29, 32-35, and 37-40 are now pending in this Application. The Applicants believe that the claims as presented are in condition for allowance. A notice to this affect is respectfully requested.

Preliminary Matters

On July 22, 2002, Attorney Barry Chapin and Attorney Christine Kuta conducted an interview with Examiner Rimell regarding a restriction requirement for the claims as filed with the application. In the interview, the Examiner agreed to withdraw requirement for restriction between group I (claims 10-18 and 20-34, as filed) and group II (claims 1-9 an 19, as filed) based on an explicit admission that claims of group I and II are obvious over each other. A response filed on November 12, 2002 included a reference to the Examiner having withdrawn the restriction requirement. The response, however, did not include a specific admission that claims of group I and II are obvious over each other.

On April 20, 2004, the undersigned conducted an interview with Examiner Sam Rimell regarding examination of the restricted claims. The undersigned wishes to thank Examiner Rimell for his time. In the interview, the Examiner indicated that because the response of November 12, 2002 did not contain a did not contain an admission that claims of group I and II are obvious over each other, the Examiner did not examine the claims of group II. The Examiner did

indicate that he would examine the claims if provided with such an admission. The Applicant has made the admission, as provided above. As such, claims 1-9 and 35 are presented for examination and claims 1-2, 5-10, 12-13, 15-18, 20-23, 25-29, 32-35, and 37-40 are now pending in this Application.

Claim Amendments

Claims 1, 2 and 5-9 been amended to clarify the nature of the invention. The claims include limitations found in previously examined claims 10, 12-13, 15-18, 20-23, 25-29, 32-34, and 36, for example. The amendments do not add new matter to the application.

Claims 10 and 20 have been amended to clarify the nature of the invention. Claims 10 and 20 clarifies a user's viewing of details of a clinical outcome such that a first user having a higher privilege level views a first portion of the clinical outcome and a second user having a lower privilege level views a second portion of the clinical outcome where the second portion of the clinical outcome is different from the first portion of the clinical outcome. Support for the amendment is located within the specification from page 27, line 13 through page 28, line 21, for example. The amendments do not add new matter to the application.

Claim 12 has been amended to replace the "if" clauses within the claim with positively recited "when" clauses. The amendment does not add new matter to the application.

Claims 21 and 28 have also been amended to clarify the nature of the invention. The amendments to claims 21 and 28 include matter found in previously examined and presently cancelled claim 24. The amendment does not add new matter to the application. Claim 21 has also been amended to replace the "if" clauses within the claim with positively recited "when" clauses. The amendment does not add new matter to the application.

Claim 37 has been added to the application and includes matter found in currently cancelled claim 24. Addition of claim 37 to the application does not add new matter to the application.

Specification Amendments

The specification has been voluntarily amended to correct typographical errors. No new matter is added to the application by the amendments.

Rejections under 35 U.S.C. §112, paragraph 4

Claims 32-34 are rejected under 35 U.S.C. §112, paragraph 4 for failing to make reference to a claim previously set forth. The Office Action indicates that claims 32-34, as filed, depend upon cancelled claim 31 and because the true dependency of the claims cannot be determined the claims cannot be considered on the merits. Claims 32-34 have been amended such that the claims now depend from pending claim 29. The amendment does not add new matter to the application.

Rejections under §102

Claims 10, 12, 13, and 20-29 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,991,728 (DeBusk, et al.), hereinafter DeBusk. Claims 10, 14-18, and 36 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,737,539 to Edelson, et al., hereinafter Edelson. The Applicant respectfully disagrees with these contentions and asserts that the present claimed invention is not anticipated by any disclosure in the DeBusk or Edelson references.

Applicant's Disclosure and Claims

Embodiments of the present invention provide a system to implement and conduct medical studies to produce medical (e.g., clinical) outcomes that can be used to treat patients that are currently participating in the study. Typically, the medical or clinical outcomes provide an indication, score or other criteria, based on the data collected in the study which may indicate, determine or evaluate the effectiveness or performance of a doctor, drug, or medical treatment as related to the treatment of a disease, sickness or other malady.

Clinical outcome data produced from systems of the invention can be generated at any time, and in real-time, during the study. The medical or clinical outcome data is therefore available for treatment of patients (e.g., provides feedback used to effect treatment of a patient) and can take into account all data entered by a doctor, patient, or other participant in the study, no matter where that person is geographically located. Thus, clinical outcomes produced from the system of the invention reflect the most up-to-date progress and results of the study.

In one arrangement, the clinical outcome system allows a user (e.g., a doctor or other medical person using the clinical outcome system) to generate and/or obtain, search and correlate clinical outcome data collected by the system. The level of study analysis provided to the user by the clinical outcome system is determined by the identity or access privileges of the user of the clinical outcome system. In such an arrangement, the system filters the study results according to the identity of the user requesting the results. For example, if a medical director sponsoring the study is requesting information from the system, the medical director may have full privileges (e.g., a higher privilege level) to see study data (e.g., a first portion of the clinical outcome) that indicates how all doctors are performing, for example, in relation to one another. In another example, if an individual doctor is requesting information from the system, the individual director may have limited privileges (e.g., a lower privilege level) to see limited amounts of the study data (e.g., a second portion of the clinical outcome).

Rejections under 35 U.S.C. §102(e)

The Office Action has rejected independent claims 10, 20, 21, and 28 under 35 U.S.C. §102(e) as being anticipated by DeBusk.

DeBusk relates to a computer implementable method and system for tracking and profiling supply usage at the procedural level in the health-care field.[1] DeBusk indicates that:

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[1] DeBusk, col. 1, l. 9-11.

> "[i]n the current health-care environment, there is increased pressure to track and minimize costs associated with the delivery of health care. One of the major areas of cost any health care facility is the supplies used during medical procedures. Often, hospitals and clinics utilized procedural packs which are designed to have all of the supplies the surging or other caregiver might need to use during the procedure. However, when these procedural packs are designed to be comprehensive, there can be considerable waste of supplies simply because they are not use during a particular procedure. Conversely, sometimes a supply is used frequently is not included in a procedural packs, thus requiring that hospital or clinic supplied labor be used to keep an inventory of such supplies and make sure that such supplies are delivered to the care site for the procedure."[2]

DeBusk provides an integrated package for the tracking of anticipated usage and actual usage of supplies, contrary to prior art tracking methods and system.[3]

DeBusk generally relates to a process for tracking of medical supply usage on a procedural level in clinical setting. In DeBusk, a user creates a procedural template that includes a partial list of supplies or resources to be used during a medical procedure. The user creates a recordation form for a given procedure where the recordation form is based upon the procedural template. The recordation form includes at least a partial listing of the anticipated supplies to be used during the procedure. The recordation form is then used to record actual supply or resource usage information based upon the actual usage of supplies or resources during the performing of the procedure. The usage information from the form is saved in a retrievable manner for use in the analysis of supply or resource usage.

The Office Action has also rejected independent claims 10 and 36 under 35 U.S.C. §102(e) as being anticipated by Edelson.

Edelson relates to a computer-implemented prescription management system to assist physicians in prescribing and reviewing drugs.[4] The prescription management system includes user computers, such as portable personal

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2 DeBusk, col. 6, l. 24-38.
3 DeBusk, col. 6, l. 39-41.
4 Edelson, col. 1, l. 13-15.

computers, connected to a host computer where the host computer provides data or data access to the user computers.[5] The system allows a physician to create an electronic prescription for a patient at a point of patient care. The system allows a physician to generate a prescription having a patient identifier, a prescribed drug, a dosage for the drug, and a patient-condition treatment specification procedure.[6] By associating a patient condition with the drug prescribed, the physician identifies and records a treatment objective associated with the drug.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[7] "The identical invention must be shown in as complete detail as is contained in the ... claim."[8]

With respect to independent claims 10, 20, 21, and 28, DeBusk does not suggest or disclose all of the elements of the Applicant's claims 10, 20, 21, and 28 and, therefore, does not anticipate the Applicant's independent claims.

DeBusk does not anticipate Applicant's claims 10 or 20 because DeBusk does not suggest or disclose a first user having a higher privilege level viewing a first portion of the clinical outcome **and a second user having a lower privilege level viewing a second portion of the clinical outcome** as claimed by the Applicant.

With respect to claims 10 and 20, the Office Action states that Fig. 4 of DeBusk illustrates the step of obtaining an identification of a user (e.g., Login) and a privilege level (e.g., password). The Office Action indicates that individuals who have passwords have higher privilege levels than those who do not have passwords. The Office Action further states that the data output is based upon the privilege level where users who do not have passwords do not receive any data output, as they are unable to log into the system. As characterized by the

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5 Edelson, col. 7, l. 10-18.

6 Edelson, col. 4, l. 30-38.

7 *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

8 *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Office Action, the system of DeBusk provides an "all-or-nothing" output of the data (e.g., a user having the password can access the data and a user not having a password cannot access the data).

DeBusk, however, does not disclose or suggest "immediately and conditionally, based on the privilege level of the user, outputting at least a portion of the clinical outcome data ... such that a first user having a higher privilege level views a first portion of the clinical outcome **and a second user having a lower privilege level views a second portion of the clinical outcome**, the second portion of the clinical outcome different from the first portion of the clinical outcome" as claimed by the Applicant. As indicated by claims 10 and 20, both a first user **and a second user** can view the clinical outcome data. Each user, however, views different portions of the clinical outcome based on different privilege levels. For example, in the case where the first user has a higher privilege level than the second user, the first user can view different portions of the clinical outcome data than the second user. However, as indicated in claim 10 and contrary to the "all-or-nothing" system in DeBusk, the second user, having a lower privilege level than the first user, **can still view a portion of the clinical outcome data** (e.g., a different portion of data than viewed by the first user) even with a lower privilege level than the first user.

Because DeBusk does not disclose or suggest "immediately and conditionally, based on the privilege level of the user, outputting at least a portion of the clinical outcome data ... such that a first user having a higher privilege level views a first portion of the clinical outcome and a second user having a lower privilege level views a second portion of the clinical outcome, the second portion of the clinical outcome different from the first portion of the clinical outcome" as claimed by the Applicant, claims 10 and 20 should be allowed to issue. Furthermore, claims 12, 13, and 15-18, that depend upon allowable claim 10, should also be allowed to issue at least for the reasons presented above.

Furthermore, with respect to Applicant's claims 21 and 28, DeBusk does not anticipate Applicant's claims 21 and 28 because DeBusk does not suggest or

disclose receiving sets of computerized medical study data and providing feedback used to effect treatment of a patient associated with at least one of the sets of computerized medical data received as claimed by the Applicant.

As indicated above, DeBusk relates to a process for tracking medical supply usage in a clinical setting. With respect to claims 21 and 28, the Office Action indicates that FIG. 7 of DeBusk illustrates inputting and logging of medical information, which corresponds to receiving sets of medical information having specific values. The Office Action further indicates that by using a clinical algorithm, the display chart of FIG. 14 is produced, which compares a doctor to another doctor on the usage of medical equipment. DeBusk, however, does not disclose or suggest the clinical algorithm "providing feedback used to effect treatment of a patient associated with at least one of the sets of computerized medical data received" as claimed by the Applicant. Furthermore, the Office Action indicates that the comparison in DeBusk can also be made for medical supplies. Again, DeBusk does not disclose or suggest how a clinical algorithm in such a case provides "feedback used to effect treatment of a patient associated with at least one of the sets of computerized medical data received" as claimed by the Applicant.

Because DeBusk does not disclose or suggest "providing feedback used to effect treatment of a patient associated with at least one of the sets of computerized medical data received" as claimed by the Applicant, claims 21 and 28 should be allowed to issue. Furthermore, claims 22, 23, and 25-27, that depend upon allowable claim 21, and claims 29 and 32-34 that depend upon allowable claim 28 should also be allowed to issue at least for the reasons presented above.

With respect to independent claim 10, Edelson does not suggest or disclose all of the elements of the Applicant's claim 10 and, therefore, does not anticipate the claim.

Edelson does not anticipate Applicant's claim 10 because Edelson does not suggest or disclose a first user having a higher privilege level viewing a first

portion of the clinical outcome **and a second user having a lower privilege level viewing a second portion of the clinical outcome** as claimed by the Applicant.

With respect to claim 10, the Office Action indicates that Edelson discloses the concept of obtaining an identification of a user and a privilege level by obtaining a password such that a ser who has a password has a higher privilege level than a user who does not have a password. The Office Action further states that a password is considered to be a higher privilege level and an individual who does not have a password is considered an individual who has a lower privilege level. As characterized by the Office Action, the system of Edelson, similar to DeBusk, provides an "all-or-nothing" output of the data (e.g., a user having the password can access the data and a user not having a password cannot access the data).

Edelson, however, does not disclose or suggest "immediately and conditionally, based on the privilege level of the user, outputting at least a portion of the clinical outcome data ... such that a first user having a higher privilege level views a first portion of the clinical outcome **and a second user having a lower privilege level views a second portion of the clinical outcome**, the second portion of the clinical outcome different from the first portion of the clinical outcome" as claimed by the Applicant. As indicated by claim 10, both a first user **and a second user** can view the clinical outcome data. Each user, however, views different portions of the clinical outcome based on different privilege levels. For example, in the case where the first user has a higher privilege level than the second user, the first user can view different portions of the clinical outcome data than the second user. However, as indicated in claim 10 and contrary to the "all-or-nothing" system in Edelson, the second user, having a lower privilege level than the first user, **can still view a portion of the clinical outcome data** (e.g., a different portion of data than viewed by the first user) even with a lower privilege level than the first user.

Because Edelson does not disclose or suggest "immediately and conditionally, based on the privilege level of the user, outputting at least a portion of the clinical outcome data ... such that a first user having a higher privilege level views a first portion of the clinical outcome and a second user having a lower privilege level views a second portion of the clinical outcome, the second portion of the clinical outcome different from the first portion of the clinical outcome" as claimed by the Applicant, claim 10 should be allowed to issue. Furthermore, claims 12, 13, and 15-18, that depend upon allowable claim 10, should also be allowed to issue at least for the reasons presented above.

If the U.S. Patent and Trademark Office deems a fee necessary, this fee may be charged to the account of the undersigned, Deposit Account No. 50-0901.

If the enclosed papers or fees are considered incomplete, the Patent Office is respectfully requested to contact the undersigned collect at (508) 366-9600, in Westborough, Massachusetts.

Respectfully submitted,

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Attorney Docket No.: OSC99-01

Dated: April 29, 2004